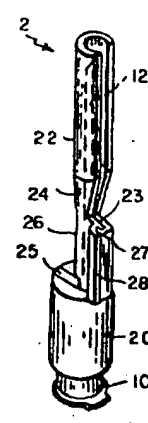
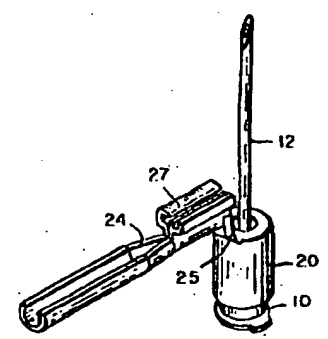




## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

<p>(51) International Patent Classification<sup>6</sup> : <b>A61M 5/32, 5/50</b></p>	<p><b>A1</b></p>	<p>(11) International Publication Number: <b>WO 98/11928</b></p> <p>(43) International Publication Date: 26 March 1998 (26.03.98)</p>
<p>(21) International Application Number: PCT/US97/10367</p> <p>(22) International Filing Date: 17 June 1997 (17.06.97)</p> <p>(30) Priority Data: 08/664,352 17 June 1996 (17.06.96) US</p> <p>(71) Applicant: SAFEGARD MEDICAL PRODUCTS, INC. [US/US]; 52 Dragon Court, Woburn, MA 01801 (US).</p> <p>(72) Inventor: KASHMER, James, S.; 63 Lynn Drive, Andover, NJ 07821 (US).</p> <p>(74) Agent: ROBINOW, Douglas, D.; Choate, Hall &amp; Stewart, Exchange Place, 53 State Street, Boston, MA 02109 (US).</p>		<p>(81) Designated States: European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).</p> <p><b>Published</b> <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i></p>
<p>(54) Title: PROTECTION DEVICE FOR SHARP OBJECTS IN PARTICULAR FOR MEDICAL NEEDLES</p> <p>(57) Abstract</p> <p>A shielding apparatus for preventing accidental contact with a sharp object such as a needle. The apparatus comprises a hinged shield, a barrel and locking mechanism. The apparatus is attached to an existing needle via a barrel or may be manufactured into the base of the syringe needle. Connected to the barrel is a hinge, a shield and a locking mechanism. The shield may pivot, via the hinge, in a direction away from needle so as to expose the needle for use. Upon completion of the use, the shield is pivoted so as to cover the needle, the shield being either permanently or temporarily locked in place via the locking mechanism, thereby preventing accidental contact.</p> <div style="text-align: right;">   </div>		

**FOR THE PURPOSES OF INFORMATION ONLY**

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece			TR	Turkey
BG	Bulgaria	HU	Hungary	ML	Mali	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MN	Mongolia	UA	Ukraine
BR	Brazil	IL	Israel	MR	Mauritania	UG	Uganda
BY	Belarus	IS	Iceland	MW	Malawi	US	United States of America
CA	Canada	IT	Italy	MX	Mexico	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NE	Niger	VN	Viet Nam
CG	Congo	KE	Kenya	NL	Netherlands	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NO	Norway	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	NZ	New Zealand		
CM	Cameroon			PL	Poland		
CN	China	KR	Republic of Korea	PT	Portugal		
CU	Cuba	KZ	Kazakhstan	RO	Romania		
CZ	Czech Republic	LC	Saint Lucia	RU	Russian Federation		
DE	Germany	LI	Liechtenstein	SD	Sudan		
DK	Denmark	LK	Sri Lanka	SE	Sweden		
EE	Estonia	LR	Liberia	SG	Singapore		

## PROTECTION DEVICE FOR SHARP OBJECTS IN PARTICULAR FOR MEDICAL NEEDLES

Background of the Invention

5 The present invention relates generally to a protective device to prevent accidental contact with the sharp surface of an object and more particularly to a protective device having a locking mechanism to prevent reuse of a needle.

10 While the accidental needle sticks have always plagued healthcare practitioners, the advent of AIDS and various other potentially lethal blood borne pathogens has increased the consequences of such needle sticks. Various attempts have been made to minimize such risks. For instance, devices have been introduced to shield the healthcare practitioner from making contact with a potentially contaminated needle, but have met with limited effectiveness.

15 A needle protection device (or shield) must meet certain criteria to be effective. First, it must provide protection to the healthcare practitioner - in other words provide an effective barrier to prevent accidental contact with the needle. Second, it must be simple to use so that the healthcare practitioner can effectively perform his or her job while at the same time avail themselves of the protection afforded by the protection device. Third, it must be cost effective so that hospitals will not incur undue costs. Fourth, it must provide protection on a time basis to shield all healthcare workers from the device.

20 In addition to the criteria listed, a protective device should also prevent exposure of the needle once disposed, be intuitive to use and accommodate a variety of needle sizes.

25 Past designs for needle protection devices included various forms of pivoting shrouds or shields that surround the needle. These designs can be divided into two broad categories based upon the locking mechanism. The first category utilized a reversible locking mechanism. This design allows the healthcare practitioner to repeatedly use the shrouding mechanism. Thus, a healthcare practitioner can engage the lock after filling the hypodermic syringe and remove the shroud just prior to injection. But this type of locking mechanism does not allow for permanent locking of the shroud about the needle, preventing reuse.

30 The second category of needle protection devices utilizes a single use locking mechanism. This design prevents the healthcare practitioner from repeatedly using

the shrouding mechanism. So a healthcare practitioner can engage the lock only after final use of the needle, just prior to disposal.

Neither of the two broad categories provide for both a temporary locking mechanism and a permanent locking mechanism. Thus, neither of the two designs  
5 allow for temporary locking of the shroud about the needle for intermediate protection and permanent locking of the shroud about the needle for final protection and disposal.

### Summary of the Invention

10 Accordingly, it is an object of the present invention to provide a needle shield that prevents accidental needle contact by the healthcare provider.

It is a further object of the invention to provide a needle shield that does not interfere with the normal operation of the syringe.

15 It is an additional object of the invention to provide a needle shield that pivots away from the needle to allow use application of the needle.

It is another object of the invention to provide a needle shield that may be used with pre-existing needles and not require redesign of the pre-existing needle.

It is another object of the invention to provide a needle shield with a temporary locking mechanism to prevent exposure of the needle.

20 It is another object of the invention to provide a needle shield with a permanent locking mechanism to prevent reuse.

It is an additional object of the invention to provide a needle shield having a locking mechanism that engages under the control of the healthcare practitioner.

25 It is a further object of the invention to provide a needle shield that is cost effective to produce.

Other objects will be obvious and will appear hereinafter. The invention comprises an article of manufacture as exemplified in the following summary and detailed description.

30 The protection device of the present invention is an assembly which is integrally molded with the a needle assembly or separately fabricated and later mated to a needle via the needle hub. The protection device includes a collar which is either compression fitted to or integrally molded with the needle hub.

Attached to the hub is a hinge that ultimately allows the shield portion of the assembly to pivot away from the needle. The hinge is mated to channel portion, which is itself mated to a transition portion connected to the shield. The channel portion is sized so as to frictionally engage the needle shaft, thereby creating a temporary locking mechanism to hold the shield next to the needle. Disposed upon the channel portion is a permanent locking mechanism. The permanent locking mechanism locks the shield in the protective position, permanently shielding the needle.

The present invention further includes variations on this design. The temporary locking mechanism may be placed in the shield assembly or disposed in the transition piece. In addition, the permanent locking mechanism may be placed in any location, including the shield, and may further comprise a one-way lock. The hinge may be formed as a single or multiple piece design.

The above mentioned objectives of the present invention will become more apparent and the invention itself better understood with reference to the following description of the embodiments of the present invention in conjunction with the accompanying drawings.

#### **Brief Description of the Drawings**

The foregoing discussion will be understood more readily from the following detailed description of the invention, when taken in conjunction with the accompanying drawings, in which:

FIG. 1 is a perspective view of a prior art shield;

FIG. 2(a) is a front perspective view of an embodiment of the invention illustrating the shield in the closed and locked position;

FIG. 2(b) is a front perspective view of an embodiment of the invention illustrating the shield in the closed and unlocked position;

FIG. 2(c) is a front perspective view of an embodiment of the invention illustrating the shield in the closed and unlocked position;

FIG. 3(a) is a side perspective view of an embodiment of the invention illustrating the shield in the open and unlocked position with the needle cover pivoted away from the needle;

FIG. 3(b) is a side view of an embodiment of the invention illustrating the shield in the open and unlocked position with the needle cover pivoted away from the needle;

5 FIG. 4(a) is a side view of an embodiment of the invention illustrating the shield in the closed and unlocked position;

FIG. 4(b) is an end view of an embodiment of the invention illustrating the shield in the closed and unlocked position;

10 FIG. 4(c) is an end view through the section A-A of FIG. 4(a) of an embodiment of the invention illustrating the shield in the closed and unlocked position;

FIG. 4(d) is a side view of an embodiment of the invention illustrating the shield in the closed and locked position; and

15 FIG. 4(e) is an end view through the section B-B of FIG. 4(d) of an embodiment of the invention illustrating the shield in the closed and locked position.

#### Detailed Description of the Preferred Embodiment

Referring to FIG. 1, a prior art needle conventional needle shield assembly mounted on a needle is illustrated. The shield assembly 1 comprises a base or  
20 collar 14 attached to a shield 16. Shield 16 is hollow cylinder disposed around the needle shaft 12. The base or collar 14 is dimensioned so as to friction fit over hub 10 in manner so as to not interfere with luer tabs 11. Removal of the shield assembly entails uncoupling base or collar 14 from hub 10 and sliding the shield 16 up and over needle 12. Conversely, replacement of the shield assembly 1  
25 entails sliding the needle 12 into cylinder 16 and friction fitting base 14 to hub 10.

30 FIGS. 2(a), 2(b) and 2(c) illustrates an embodiment of the present invention as utilized in conjunction with a pre-existing needle. The shield assembly 2 of the present invention is comprised of a barrel 20 that permanently holds the assembly 2 to the needle hub 10. The barrel 20 and the hub 10 may be fictionally fit to one another or molded into a single unit. Above the barrel 20 is the locking mechanism which connects to the barrel 20 via hinge 25. The locking mechanism includes temporary lock formed by a channel portion 26 sized to frictional fit the

needle 12. A slit 23 in channel portion 26 allows passage of the needle 12 when channel portion 26 is pivoted about the hinge 25. A permanent lock, disposed on opposite sides of slit 23, is formed by a pivoting latch 27 and a catch 28.

5 Above the channel portion is a transition piece 24 which allows for a transition between the channel portion 26 and shield 22. Shield 22 is sized and shaped to enclose the needle 12 so as to prevent accidental contact. As illustrated, the shield 22 is a cylindrical portion extending beyond the tip of the needle 12 and substantially surrounding the needle 12.

10 FIG. 2(a) illustrates the shield assembly 2 in the closed and locked position with the shield 22 enclosing the needle 12 and the locking mechanism 27 and 28 locked. As illustrated, the needle 12 is disposed in the channel 26 and enclosed by the latch 27 engaged to the catch 28. FIG. 2(b) illustrates the shield assembly 2 in the closed and unlocked position with the locking mechanism now in the unlocked position. FIG. 2(c) is a cutaway with the shield 22 removed, illustrating the shield  
15 assembly 2 in the closed and unlocked position.

The shield assembly 2 is designed to pivot away from the needle 12 via a hinge 25. FIGS. 3(a) illustrates the pivoting action of the shield assembly into the open and unlocked position. In this position, the needle 12 is exposed for use. FIG. 3(b) is a side view of the assembly in the open position. Again, in this  
20 position the needle is unobstructed.

In order to cover the needle, the shield 22 is pivoted into the closed position via hinge 25. FIGS. 4(a) is a side view illustrating the assembly in the closed and closed position. In this position, the needle 12 is temporarily secured in channel portion 26. Friction between the needle 12 and the channel portion 26  
25 prevents the shield 22 from accidentally pivoting into the open position. The shield 22 is not permanently locked, but rather temporarily locked in this configuration. By overcoming the friction between the needle 12 and the channel portion 26, the healthcare provider can once again pivot the assembly into the open position, exposing the needle. Thus, the present invention allows the shield assembly to  
30 cover the needle multiple times, such as prior to filling, after filling but prior to injection, and after injection but prior to disposal.

Once the healthcare provider has determined that the procedure is complete and that the needle should be disposed, the shield assembly is permanently locked in the closed position. With reference to FIGS. 2(b), 4(a), and 4(b) the needle 12 is first captured into the channel assembly 26. Next, the locking mechanism is engaged by swinging the pivoting latch 27 to the catch 28 which form the permanent lock. FIGS. 2(a), 4(d) and 4(e) illustrate how latch 27 engages and locks into catch 28. It is preferred that the lock formed by the latch 27 and the catch 28 be of a one-way design so that, once engaged, the latch 27 cannot be separated from the catch 28. Thus, the preferred design for the lock assembly prevents unlocking once the permanent lock is engaged. Once the shield assembly is in the locked closed position, the needle may be disposed.

Variations on the design are envisioned. For instance, in the preferred design, the hinge 25 is formed as a single piece "living hinge," but a two piece hinge is also contemplated. The preferred design for the temporary lock is the channel 26 which fictionally engages the needle 12, but alternative designs utilizing temporary locks disposed in shield 22 are also contemplated. In addition, the permanent lock in the preferred embodiment utilizes a latch 27 and a catch 28 disposed on opposite sides of the channel 26, but may also be composed of various permanent locks disposed in the shield 22 and may also utilize various shapes for the latch 27 and the catch 28.

The shield assembly of the preferred embodiment can be constructed from a thermoplastic material via an injection molding process. The shroud may be integrally molded with the needle hub or may be molded separately and press fit to needle hub. The preferred material would be of the polyolefin family, which includes polyethylene and polypropylene, because of the embodiments "living hinge." One of ordinary skill in the art would understand to select the final choice of material based upon such factors such as construction method, material compatibility, cost, etc.

It should be understood that other embodiments could be created with variations in shape and size. Although the present invention has been described in detail with reference only to present preferred embodiments, it will be appreciated by one of ordinary skill in the art that various modifications can be made without



- departing from the invention. Accordingly, the invention is limited only by the following claims.

What is claimed is:

Claims

- 1
- 2       1.     An apparatus to cover a needle comprising,
- 3               a collar adapted to engage a first portion of the needle;
- 4               a shield adapted to cover at least a second portion of the needle,
- 5       said shield in communication with said collar via a hinge, said hinge
- 6       allowing said shield to pivot away from said second needle portion; and
- 7               a locking mechanism adapted to provide a temporary locking state
- 8       and a permanent locking state, said locking mechanism adapted to engage
- 9       said needle in said temporary locking state when said shield is pivoted so as
- 10      to cover said second needle portion, said locking mechanism further
- 11      adapted to controllably engage said needle within said shield in said
- 12      permanent locking state.
- 13
- 14      2.     The apparatus of claim 1 wherein said collar is further adapted to slide
- 15      over said needle.
- 16
- 17      3.     The apparatus of claim 1 wherein
- 18               said needle further has an outer needle diameter, and
- 19               said locking mechanism has a channel portion having an internal
- 20      channel dimension approximately equal to said outer needle diameter so as
- 21      to frictionally contact said needle thereby providing said temporary locking
- 22      state.
- 23
- 24      4.     The apparatus of claim 1 wherein said locking mechanism further
- 25      comprises a one-way lock adapted to enclose said needle thereby providing said
- 26      permanent locking state.
- 27
- 28      5.     The apparatus of claim 4 wherein said one-way lock further comprises a
- 29      latch and a catch for said latch.
- 30
- 31      6.     The apparatus of claim 5 wherein said latch and said catch are disposed on
- 32      said channel.

- 1 7. The apparatus of claim 4 wherein said one-way lock is integral to said  
2 shield.
- 3
- 4 8. The apparatus of claim 4 wherein said channel is disposed between said  
5 hinge and said shield.
- 6
- 7 9. The apparatus of claim 6 where said locking mechanism is disposed between  
8 said hinge and said shield.
- 9
- 10 10. The apparatus of claim 1 wherein said shield surrounds at least half a  
11 circumference of a circle orthogonal to an axial direction of said needle.
- 12
- 13 11. The apparatus of claim 1 wherein said shield has a substantially cylindrical  
14 cross sectional shape.
- 15
- 16 12. The apparatus of claim 1 wherein said shield has a substantially rectangular  
17 cross sectional shape.
- 18
- 19 13. The apparatus of claim 1 wherein said locking mechanism is internal to  
20 said shield.
- 21
- 22 14. The apparatus of claim 1 wherein said collar, said shield, said hinge and  
23 said locking mechanism are formed of as a single unit.
- 24
- 25 15. An apparatus to cover a needle comprising,  
26 collar means adapted to engage a first portion of the needle;  
27 shield means adapted to cover at least a second portion of the  
28 needle, said shield in communication with said collar means via hinge  
29 means, said hinge means allowing said shield means to pivot away from  
30 said second needle portion; and  
31 locking means adapted to provide a temporary locking state and a  
32 permanent locking state, said locking means adapted to engage said needle

1 in said temporary locking state when said shield means is pivoted so as to  
2 cover said second needle portion, said locking means further adapted to  
3 controllably engage said needle within said shield means in said permanent  
4 locking state.

5  
6 16. The apparatus of claim 15 wherein said collar means is further adapted to  
7 slide over said needle.

8  
9 17. The apparatus of claim 15 wherein  
10 said needle further has an outer needle diameter, and  
11 said locking means having a channel portion having an internal  
12 channel dimension approximately equal to said outer needle diameter so as  
13 to fictionally contact said needle thereby providing said temporary locking  
14 state.

15  
16 18. The apparatus of claim 15 wherein said locking means further comprises a  
17 irreversible locking means adapted to enclose said needle thereby providing said  
18 permanent locking state.

19  
20 19. The apparatus of claim 16 wherein said irreversible locking means further  
21 comprises a latch and a catch for said latch.

22  
23 20. The apparatus of claim 16 wherein said irreversible locking means is  
24 internal to said shield means.

25  
26 21. The apparatus of claim 16 wherein said channel is disposed between said  
27 hinge and said shield.

28  
29 22. The apparatus of claim 16 where said locking means is dispose between  
30 said hinge means and said shield means.

1     23.     The apparatus of claim 15 wherein said shield means surrounds at least half  
2     a circumference of a circle orthoganal to an axial direction of said needle.

3

4     24.     The apparatus of claim 15 wherein said shield means has a substantially  
5     cylindrical cross sectional shape.

6

7     25.     The apparatus of claim 15 wherein said shield means has a substantially  
8     rectangular cross sectional shape.

9

10    26.     The apparatus of claim 15 wherein said locking means is internal to said  
11    shield means.

12

13    27.     The apparatus of claim 15 wherein said collar means, said shield means,  
14    said hinge means and said locking means are formed of as a single unit.

15

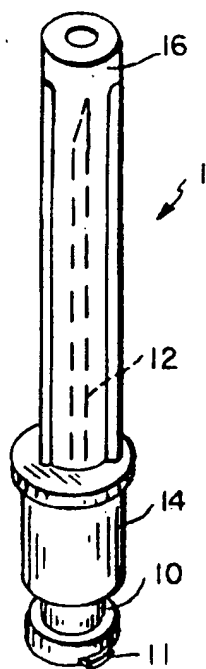


FIG. 1 PRIOR ART

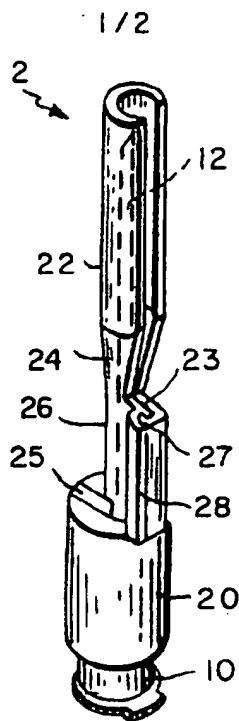


FIG. 2(a)

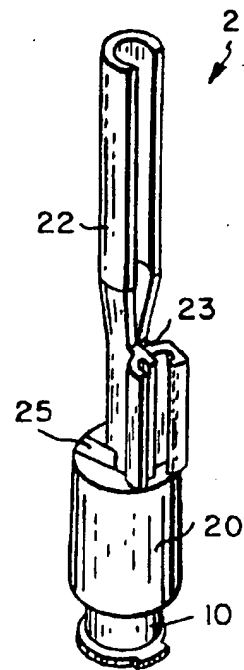


FIG. 2(b)

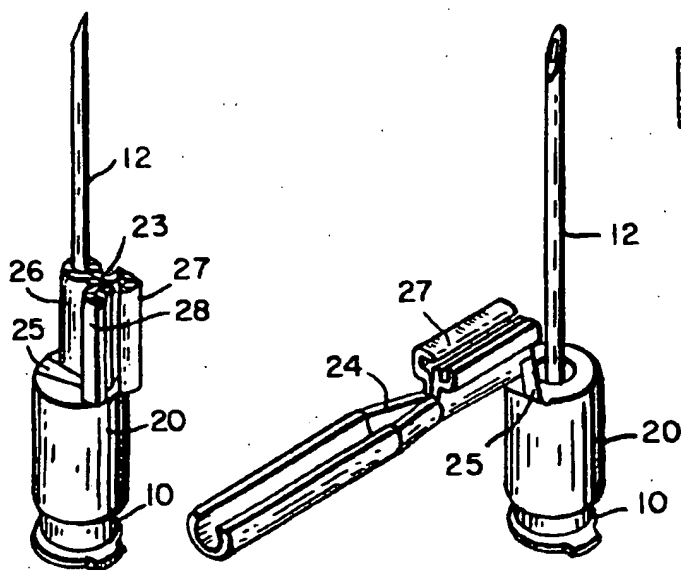


FIG. 2(c)

FIG. 3(a)

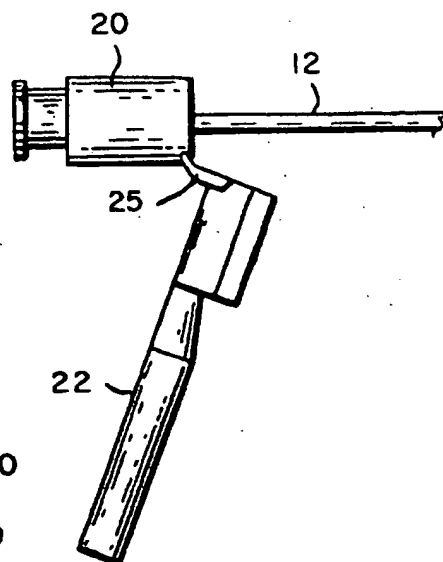


FIG. 3(b)

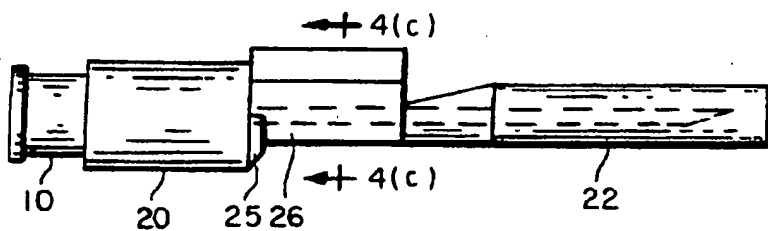


FIG. 4(a)

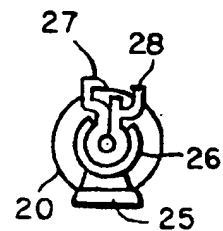


FIG. 4(b)

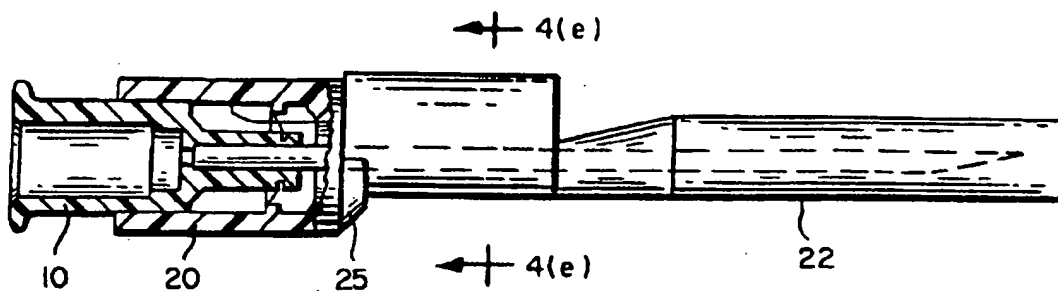


FIG. 4(d)

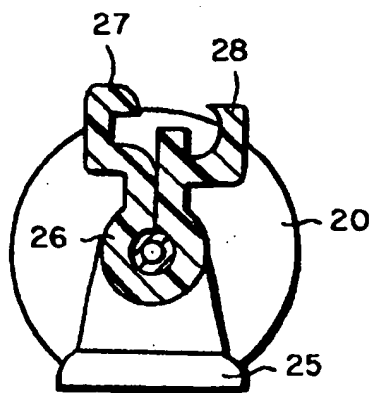


FIG. 4(c)

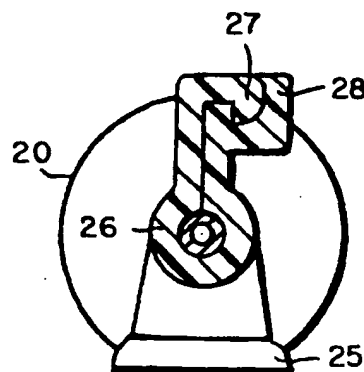


FIG. 4(e)

# INTERNATIONAL SEARCH REPORT

Int. .onal Application No

PCT/US 97/10367

**A. CLASSIFICATION OF SUBJECT MATTER**  
IPC 6 A61M5/32 A61M5/50

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 91 09639 A (STEER) 11 July 1991  see page 11, line 7 - line 14 see page 12, last paragraph - page 13, paragraph 1 see figures 18-20	1,2,4-7, 9,12-16, 18-22, 25-27
Y	---	3,10,17, 23
X	WO 91 09638 A (STEER) 11 July 1991  see page 3, last paragraph - page 4, paragraph 1 see figures 5-12  ---	1,4,5,7, 12,14, 15,18, 25-27
	-/--	

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

\* Special categories of cited documents:

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- "&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
9 February 1998	19/02/1998
Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl Fax: (+31-70) 340-3016	Authorized officer  Sedy, R



# INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 97/10367

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No
X	EP 0 340 892 A (COLE) 8 November 1989  see column 4, line 2 - line 43; figures ---	1,4-7, 14,15, 18,26,27
Y	US 3 658 061 A (HALL) 25 April 1972  see column 2, line 13 - line 16; figure 1 ---	3,10;17, 23
A		8
A	EP 0 460 914 A (PATERSON) 11 December 1991 see column 4, line 39 - line 43; figure 1 -----	11,24

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 97/10367

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9109639 A	11-07-91	GB 2239604 A	10-07-91
		GB 2240273 A	31-07-91
		GB 2240477 A	07-08-91
		AU 7045591 A	24-07-91
		AU 7067091 A	24-07-91
		CN 1054540 A	18-09-91
		CN 1054720 A	25-09-91
		WO 9109638 A	11-07-91
		GB 2239607 A	10-07-91
		AU 7048391 A	24-07-91
		WO 9109637 A	11-07-91
WO 9109638 A	11-07-91	GB 2240273 A	31-07-91
		AU 7045591 A	24-07-91
		AU 7067091 A	24-07-91
		CN 1054540 A	18-09-91
		CN 1054720 A	25-09-91
		WO 9109639 A	11-07-91
		GB 2239607 A	10-07-91
EP 340892 A	08-11-89	US 4944731 A	31-07-90
		GB 2217991 A	08-11-89
US 3658061 A	25-04-72	NONE	
EP 460914 A	11-12-91	AT 129905 T	15-11-95
		DE 69114362 D	14-12-95
		DE 69114362 T	18-07-96
		US 5116325 A	26-05-92